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## A New Adventure for Wholly Foreign Invested Hospital

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### 1. Brief Summary of Development of Wholly Foreign-Invested Hospitals Regulations in the People's Republic of China ("PRC")

Wholly foreign-invested hospitals have always been a sector under relatively strict regulation in the PRC, except for limited cases as pilots. One of the very first legal documents allowing foreign investors to set up wholly foreign invested hospitals is the *Tentative Administrative Measures on Wholly Foreign Invested Medical Institutes of China (Shanghai) Pilot Free Trade Zones* issued on 13 November 2013. This regulation focuses on the procedures and conditions for establishing wholly foreign-owned hospitals in Shanghai Free Trade Zone ("**FTZ**").

On 27 August 2014, the National Health and Family Planning Commission and the Ministry of Commerce jointly published a *Circular relating to the pilot work for establishment of wholly foreign-invested hospitals*, which enlarges the pilot area for wholly foreign invested hospitals to the 7 provinces and municipalities, i.e. Beijing, Tianjin, Shanghai, Jiangsu Province, Fujian Province, Guangdong Province and Hainan Province. (Please see our newsletter: [A Warning for Foreign Hospitals](#)).

However, immediately in 2015 the *Negative List for Foreign Investment Industries* ("**Negative List**") included medical institutions into the limited catalogue. In 2017 version of the Negative List, it was clarified that foreign investors can only participate in hospitals by means of Sino-foreign equity or contractual joint venture. Therefore, up till now, only limited number of wholly foreign-invested hospitals have been successfully established in the PRC, for instance the Japan-based Shanghai Towako Hospital established in Shanghai FTZ<sup>1</sup>. Foreign investors in healthcare sector had to set up hospitals in China in the form of Sino-foreign joint ventures<sup>2</sup> or some of them had to choose to set up joint venture by first setting up a Chinese company acting as the Chinese party. In fact, the majority of cooperation in healthcare area is still in the form of contractual cooperation instead of foreign direct investment, such as the recent contractual cooperation between Rui Jin Hospital and French National Institute of Health and Medical Research (INSERM<sup>3</sup>).

### 2. New Regulation on Opening-up in the Medical Sector

On 7 September 2024, the Ministry of Commerce, the National Health Commission, and the National Medical Products Administration announced the *Circular on Launching the Pilot Program for Expanding the Opening-up in the Medical Sector* (the "**Circular**"), allowing the establishment of wholly foreign-owned hospitals in Beijing, Tianjin, Shanghai, Nanjing, Suzhou, Fuzhou, Guangzhou, Shenzhen and the entire Hainan Island<sup>4</sup> (excluding hospitals practising traditional Chinese medicine and mergers and acquisitions of public hospitals). (Note that according to the latest Negative List (2024 version) effective as of 1 November 2024, foreign investors can still participate in hospitals only by means of

Sino-foreign joint venture, which is the same case compared with the 2020 version of the Negative List and the subsequent Negative Lists issued since then). There are seemingly contradictory regulations between the Circular and the Negative List (2024 Version). Despite the above, the Circular opens again a new opportunity for foreign investors in the development of wholly foreign-owned hospitals in China.

We noticed from public resources that soon after the issue of the Circular, Singapore based TTG Group signed cooperation agreement with Baiyun District Government of Guangzhou Municipality on 8 November 2024. According to such cooperation agreement, TTG Group will invest one billion RMB for initial investment to establish TTG International Hospital in Baiyun District (Guangzhou), which will anticipatedly become the first wholly foreign-invested hospital newly established after the issue of the Circular<sup>5</sup>. The effect of the Circular in attracting foreign investors into the medical sector in the PRC is evident.

Also, based on our recent experiences, local governments, such as Shanghai Municipality, have been always strongly encouraging the development of hospitals with foreign investors, especially high-end foreign invested hospitals, in order to increase the high-level healthcare service in Shanghai.

It is worth noticing that in June 2024, the National Development and Reform Commission and other authorities issued the *Measures for Creating New Consumption Scenarios and Fostering New Growth Points in Consumption*. Such document encourages the promotion of the growth of consumption in healthcare area and encourages regions and medical institutions with suitable conditions to provide specialized medical services, and supports private businesses to provide high-end medical services. Therefore, high-end medical services are encouraged by national strategy and are key growth points in promoting consumption. Moreover, according to the national-level strategy of *Healthy China 2030 Outlines* promulgated by the State Council as early as in 2016, China aims to gradually expanding the scope of foreign-invested medical institutions. Also, medical institution is listed as an encouraged item in the *Catalogue of Encouraged Industries for Foreign Investment* (latest 2022 version).

To read such documents together with the Circular, high-end services to be provided by wholly foreign-invested hospital are encouraged and supported by the national strategy.

### **3. Highlights for Wholly Foreign-Invested Hospitals**

According to the Circular, the specific conditions for establishing wholly foreign-owned hospitals, as well as the detailed requirements and procedures, will be announced separately.

On 1 November 2024, the National Health Commission of the PRC and other relevant departments issued the *Pilot Programme for Opening-up in the Field of Wholly-Owned Hospitals* ("**Pilot Programme**"). On 29 November 2024, the National Health Commission of the PRC also published on its website its interpretations and replies regarding the Pilot Programme<sup>6</sup>.

The Pilot Programme specifies the requirements for foreign investors and wholly foreign-owned hospitals, especially the following:

#### **a) Qualification for Foreign Investors**

Foreign investors shall be legal persons capable of independently assuming civil liability, with experience in directly or indirectly engaging in healthcare investment and management.

Foreign investors shall meet specific conditions, such as ability to provide internationally advanced hospital management concepts, management models and service models, and shall have the ability to provide medical technology and equipment at the leading international level, etc.

The Pilot Programme does not stipulate specific requirements regarding the years of engaging in healthcare industry or registered capital, etc. These requirements might be further stipulated in local regulations to be enacted by each province.

## **b) Prohibited Hospital Types and Treatment Activities**

The Pilot Programme clearly stipulates that certain kinds of wholly foreign-invested hospitals are not allowed to be established by foreign investors, including:

- (1) psychiatric hospitals;
- (2) infectious disease hospitals;
- (3) haematology hospitals;
- (4) Chinese traditional medicine hospitals;
- (5) combined Chinese and western medicine hospitals; and
- (6) ethnic minority medicine hospitals.

Furthermore, wholly foreign-owned hospitals are not allowed to register "haematology" as a medical treatment item in its medical institution practice licence.

Certain treatment activities with high medical or ethnical risks are not allowed to be carried out by wholly foreign-invested hospitals, mainly including<sup>7</sup>:

- (1) human organ transplantation techniques;
- (2) assisted human reproduction techniques;
- (3) prenatal screening and prenatal diagnostic techniques;
- (4) psychiatric inpatient treatment; and
- (5) experimental treatment with new techniques for tumour cell therapy, etc.

## **c) Nature, Types and Grade of Hospitals**

Wholly foreign invested hospitals can be established in the form of either a profitable purpose hospital or a non-profitable purpose hospital.

The types of hospitals authorized to be set up include comprehensive hospitals, specialized hospitals and rehabilitation hospitals. This provision implies the types of medical institutions authorized for wholly foreign investment are limited to the above-mentioned three types of hospitals. Other types of medical institutions, such as maternal and child health centers, clinics, ordinary or specialty out-patient departments, etc. are not included in the scope of the Pilot Programme. This means that the setup of those other types of medical institutions than the three types above mentioned shall still be in the form of Sino-foreign joint ventures, unless the Pilot Programme may further enlarge the types of medical institutions in the future.

Pilot Programme further stipulates that the level of hospital is Grade III<sup>8</sup>. The *Medical Institution Basic Standards* (trial, 2017 version) impose specific statutory requirements for the set-up of each type of hospitals. For instance, the set-up of a Grade III comprehensive hospital shall require no less than 500 inpatient beds; the set-up of a Grade III dental hospital shall require no less than 60 dental treatment chairs and no less than 50 inpatient beds. There are also other requirements in terms of personnel, equipment and setting up of departments etc. In order to meet such statutory requirements, financial investment in various aspects should be considered.

## **d) Personnel**

Wholly foreign-owned hospitals are allowed to employ foreign physicians, physicians from Hong Kong, Macau and Taiwan, and other health professionals and technicians from Hong Kong and Macau for short-term practice in the PRC.

However, the proportion of number of Chinese (mainland) staff for both management in the whole hospital, and health professionals and technicians should not be less than 50%.

## **e) Healthcare Information System and Data Storage**

The hospital information management system must be connected to the local medical treatment monitoring and supervision platform and the data storage servers for electronic medical record and medical equipment must be located in China. This is in line with the current requirements.

#### **f) Insurance**

Wholly foreign invested hospitals can apply to become medical insurance reimbursement designated hospitals in order to apply the national medical insurance reimbursement system. Also, wholly foreign-invested hospitals are encouraged to cooperate with domestic and foreign commercial healthcare insurance companies.

#### **g) Approval Procedure**

The application for setting up of wholly foreign invested hospitals shall be subject to the approval of the health department at local district/city level which will transmit the application to the healthcare department at provincial level for approval. Upon approval, an approval certificate and a medical institution practice licence will be issued.

A medical institution practice licence is valid for a term of five years and can be renewed upon re-application prior to its expiry date.

It can be noted that there are certain restrictions imposed on wholly foreign-invested hospitals, mainly in terms of types of hospitals and treatment activities. A foreign investor should decide on the market positioning of wholly-foreign-invested hospitals before its investment decision is made, regarding whether it should be a comprehensive hospital or specialized hospital, and what kind of medical services it plans to provide, by taking into account the above-mentioned requirements provided in the Pilot Programme.

### **4. Challenges and Opportunities**

Apart from the above newly-issued requirements, another major challenge that foreign investors usually face in setting up wholly foreign-invested hospitals in the PRC is the business model and profitability compared with the level of investment. Since the medical service to be provided by wholly foreign-invested hospital will not be covered by the social insurance package of the PRC, the expenses to be spent in wholly foreign-invested hospital will be borne by the patients themselves or reimbursed by commercial insurance<sup>9</sup>. Commercial medical insurance is still premature in the PRC, and there are limited number of people who have purchased commercial medical insurance. Therefore, the number of patients who are willing to go to wholly foreign-invested hospital would probably be affected. This explains to some extent that specialized hospitals are more attractive for foreign investment than comprehensive hospitals, due to its profitability.

We noticed that more advanced insurance package products are being developed and offered to patients, such as Hu Xiang Bao which is a type of medium-end medical insurance, developed by CPIC (China Pacific Insurance (Group) Co., Ltd) in response to the *Several Measures of Shanghai Municipality to Further Improve the Multiple Payment Mechanism to Support the Development of Innovative Medicines and Devices* (effective as of 28 July 2023). Hu Xiang Bao includes into its coverage services provided by international medical department of public hospitals and proton and heavy ion related medical treatment. It can be anticipated that in the future, more advanced commercial insurance products will be available.

Besides, clinical trials can also be one kind of activities authorized to be carried out in wholly foreign invested hospitals as under PRC Law, Grade II hospitals or above can be qualified as clinical trial institution for pharmaceuticals and medical devices.

In light of the above, the PRC government has sent out signals to encourage foreign investors to invest in hospitals in the PRC. More detailed local regulations are expected to be promulgated to support the development of wholly foreign-owned hospitals. It cannot be excluded that the current Negative List (2024 version) would be further revised in terms of foreign invested medical institutions in order to meet this policy trend. For foreign investors, the major considerations for setting up their wholly foreign-invested hospitals will be its market positioning and a carefully designed business model.

With the Circular and Pilot Programme, foreign investors are facing a new adventure in the development of wholly foreign-invested hospitals in China. Given the challenges and opportunities in

the healthcare industry, it is advisable for foreign investors to revert to professional legal advisors to assess the appropriate business model and regulatory constraints before its investment.

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<sup>1</sup> It should be pointed out what we addressed above refers to those hospitals wholly invested by foreign investors other than those from Hong Kong and Macau. For investors from Hong Kong and Macau, since the *Tentative Measures for Administration of Foundation of Wholly-invested Hospitals in Mainland China by Hong Kong and Macau Service Providers* (effective as of 1 January 2011), it has been allowed that upon approval, Hong Kong and Macau service providers can set up wholly-invested hospitals in the PRC. In practice, almost all wholly-foreign invested hospitals established in China are actually wholly invested by investors from Hong Kong and Macau. For instance, Shanghai Artemed Hospital, Shanghai Gamma Knife Hospital, Shanghai Delta Health Hospital, etc.

<sup>2</sup> There are currently around 60 foreign invested joint ventures existing in China. (source: <http://www.nhc.gov.cn/yzygj/s3578/202411/35d13cd9cc4b4613aac66de37841ab10.shtml>)

<sup>3</sup> Institut national de la santé et de la recherche médicale (source: <https://sghexport.shobserver.com/html/baijiahao/2024/10/16/1442965.html>)

<sup>4</sup> Subject to the *Hainan Free Trade Port Law* effective as of 10 June 2021.

<sup>5</sup> Source: [https://www.by.gov.cn/zwgk/ldzc/qzf/pzj/gz/gk/content/post\\_9970344.html](https://www.by.gov.cn/zwgk/ldzc/qzf/pzj/gz/gk/content/post_9970344.html).

<sup>6</sup> Source of the interpretation: <http://www.nhc.gov.cn/yzygj/s3578/202411/01c02be15b104c23a900b0cf4f6199dd.shtml> and source of the replies <http://www.nhc.gov.cn/yzygj/s3578/202411/35d13cd9cc4b4613aac66de37841ab10.shtml>

<sup>7</sup> Subject to the *Regulation of the People's Republic of China on the Administration of Human Genetic Resources* effective as of 1 July 2019 and revised on 10 March 2024.

<sup>8</sup> In 2023, there are in total 38,000 hospitals in China, in which there are 3,855 Grade III hospitals (source: <http://www.nhc.gov.cn/yzygj/s3578/202411/35d13cd9cc4b4613aac66de37841ab10.shtml>).

<sup>9</sup> It should be pointed out that for those hospitals that are wholly invested by Hong Kong or Macau investors, some of them have been covered by social insurance to certain extent, for instance Shanghai Artemed Hospital is covered as second-grade settlement hospital.